510(k) Summary
(As required by 21 CFR 807.92)

NOV 21 2002

Premarket Notification Number: Applied for

1. Submitter's Identification:

Acute Ideas Co., Ltd.
3F, No.11, Lane 35, Jihu Road
Neihu Dist., Taipei, Taiwan
Tel: +886-2-87514868
Fax: +886-2-87515868
Contact: Mr. Albert Chen

Date Summary Prepared: Oct. 17, 2002

2. Name of the Device:

Digital Thermometer Classic Type and Flexible Type

3. Predicate Device Information:

1) KEJUMP Digital Clinical Thermometer, K903590, K-Jump Health Co., Ltd.
2) Flexible Tip Digital Thermometer, K974195, K-Jump Health Co., Ltd.

4. Device Description:

The Digital Thermometer is an electronic clinical thermometer intended for the determination of oral, axillary, and rectal body temperature determination in humans. Classic type and Flexible type have the same indication for use; however, Flexible type has a flexible tip.

5. Intended Use:

The device measures the human body temperature from oral, axillary, and rectal. The device is reusable and intended for clinical or home use on people of all ages.

6. Comparison to Predicate Devices:

   The Digital Thermometer Classic type and Flexible type are substantial equivalence to K-Jump's Digital Clinical Thermometer and Flexible Tip Digital Thermometer.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

   In terms of physical requirements and operating parameters, the Digital Thermometer Classic type and Flexible type conforms to ASTM E1112, "Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature", as well as IEC 60601-1 and IEC 60601-1-2 requirements.

8. Discussion of Clinical Tests Performed:

   Controlled human clinical studies ware not conducted using the Digital Thermometer Classic type and Flexible type and predicate devices.

9. Conclusions:

   The Digital Thermometer Classic type and Flexible type have the same intended use and similar technological characteristics as predicate devices. Moreover, any differences in their technological characteristics that do exist would not have a significant effect on the safety or effectiveness of the device. Thus, the Digital Thermometer Classic type and Flexible type are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2002

Mr. Albert Chen
General Manager
Acute Ideas Company Limited
3F, No. 11, Lane 35, Jihu Road
Neihu Dist., Taipei,
TAIWAN

Re: K023711
Trade/Device Name: Digital Thermometer Classic Type and Flexible Type
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: October 29, 2002
Received: November 4, 2002

Dear Mr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: .....

Device Name: Digital Thermometer Classic Type and Flexible Type

Indications for Use:

- The Device measures the human body temperature from oral, axillary, and rectal. The device is reusable and intended for clinical or home use on people of all ages.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023711

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)